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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/074,715 | 02/13/2002 | Jack A. Maggiore | BMT-107 | 6774 |
| 7590 | 12/03/2004 | | EXAMINER | |
| OLSON & HIERL, LTD. 36th Floor 20 North Wacker Drive Chicago, IL 60606 | | | GABEL, GAIENE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,715

Applicant(s)

MAGGIORE ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 23-30, 33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1, claims 1-22, 31, and 32, without traverse, filed 10/14/04 is acknowledged and has been entered. Claims 23-30, 33, and 34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-34 are pending. Claims 1-22, 31, and 32 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 6, 8, 14, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in reciting, "EDTA". Acronyms or abbreviations must be fully defined and recited at least one time in a set of claims.

Claim 6 is indefinite in reciting non-idiomatic expression in reciting "includes".

The term "comprises" is suggested but not required to overcome this rejection.

Claim 8 is indefinite in reciting non-idiomatic expression in reciting "includes".

The term "comprises" is suggested but not required to overcome this rejection.

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Claim 14 is indefinite in reciting, "EDTA". Acronyms or abbreviations must be fully defined and recited at least one time in a set of claims.

Claim 19 is indefinite in reciting non-idiomatic expression in reciting "includes". The term "comprises" is suggested but not required to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Steaffens et al. (US Patent 6,579,688).

Steaffens et al. disclose a stabilizing composition suitable for preserving biological fluid specimen having polypeptides and antigens (see Abstract and column 3, lines 55-64). The composition consists essentially of ethylenediaminetetraacetic acid or EDTA as chelating agent and ethanol as cell lysing or dispersing agent. The composition also includes a preservative such as butylated hydroxy anisole or BHA and sodium azide. The composition may also include ethylene glycol (antifreeze agent). See column 4, line 33 to column 5, line 6, and column 2, lines 7-43. Steaffens et al. teach adding EDTA concentrations of 0.05 to about 0.5 weight percent (0.01mM to

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100mM), cell lysing agent concentration of 5 to about 25 percent (0.1% to 30% w/v), and a preservative concentration of 0.1 weight percent (0.01% to 10% w/v) (see column 6, lines 12-43).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 19-22, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steaffens et al. (US Patent 6,579,688) in view of Figard (US Patent 5,616,460).

Steaffens et al. has been discussed supra. Steaffens et al. differ from the instant invention in failing to disclose a concentration of up to about 50 weight percent of

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antifreeze agent. Steaffens et al. also fail to teach incorporating the preserving composition into a kit format (packaged form).

Figard discloses a buffer composition for reagents wherein ethylene glycol (anti-freeze agent) is used for its superior ability to preserve binding capacity of antibodies to antigens in biological fluids. Figard teaches use of ethylene glycol at concentrations of up to 50 weight percent (4% to about 8% weight per unit volume) (see column 4, lines 53-67). Figard teaches incorporating the reagent into a kit format (reagent packaged form) (see column 6, line 62 to column 7, line 2)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use anti-freeze agent concentration as taught in the composition of Figard in the preserving composition taught by Steaffens because Figard found that ethylene glycol used in such concentrations provide superior preserving capacity in binding interactions between polypeptides. Additionally, specific concentrations of elements in a preserving composition encompass result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a

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known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since prior art teaches that different concentrations of distinct elements in a preserving reagent often vary according to the sample being stored, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the elements contained in the composition disclosed by the prior art by normal optimization procedures.

It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the preserving composition as taught by Steaffens into a kit arrangement as taught by Figard because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

5. No claims are allowed.

Remarks

6. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Haywood et al. (US 2003/0087423 A1) teach a reagent for treating biological samples. The reagent is an alcohol solution which includes stabilizing agents, lysing agents, preservatives, and chelating agents (see page 6).

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Tyrrell (US Patent 6,406,919) teaches a blood collection device which includes diluting liquid reagent compositions that have stabilizing or preserving effect (see column 5).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
November 19, 2004

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Christopher L. Chin
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PRIMARY EXAMINER
GROUP 1800 /641
11/19/04